

Appl. No. 09/992,957

REMARKS

Rejection of the claims under 35 USC § 102:

Claims 1-6 and 9-12 have been rejected under 35 U.S.C. 102(b) as being anticipated by either one of Liu *et al* (1999) or Zhang *et al.* (1999).

Liu *et al.* and Zhang *et al.* disclose a method for delivering plasmid DNA to a liver cell via injection into tail vein and expressing the plasmid DNA in the liver cell. Liu *et al.* list several potential uses for their technique on page 1265, first column, but do not mention genetic immunization, genetic vaccination, or generation of an immune response. Similarly, Zhang *et al.* list potential uses for their technique without mention of generation of an immune response (page 1737, first column, last paragraph).

Applicants have amended their claims to recite:

generating the immune response in a majority of mammals injected for the purpose of utilizing the immune response, such use is selected from the list consisting of: immunizing the mammals, vaccinating the mammals; inducing a cellular immune response, inducing a humoral immune response, producing antibodies specific to said antigen, and producing immune cells that produce antibodies to the antigen.

The claims now positively recite the "use" of their method. Generating an immune response for the purpose of utilizing that immune response is not contemplated by the Liu or Zhang references. Those references simply imply a probable immune response as a byproduct of their injection, however, they are not aware of and do not use the immune response. In contrast, Applicants purposely create the immune response and use it as part of their method. Therefore, Applicants believe that the §102 rejection is obviated.

Support for the amendments can be found in the specification as follows: vaccinating the mammal (page 6 lines 16-30 and page 32 lines 1-19); immunizing the mammal (page 18 lines 15-26); inducing a cellular or humoral immune response (page 4 lines 5-20, page 19 lines 13-17, and page 30 line 34 to page 31 line 7); generating antibodies or antibody producing cells (page 10 line 21 to page 11 line 25, page 20 lines 18-31, and page 36 lines 17-34).

Rejection of the claims under 35 USC 103:

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Claim 7 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* and Zhang *et al.* in view of Smyth-Templeton *et al.* As discussed in the previous section, Applicants suggest that the amendment obviates this §103 rejection.

Rejection of the claims under 35 USC 102:

Claims 25-27 are rejected under §102(b) as being anticipated by either Böhm *et al.* or Hurpin *et al.*

Applicants have amended the claims to obviate the rejection. Hurpin *et al.* observed an immune response after injection of viral vector into the tail vein of mice. Plasmid DNA was not delivered through the vasculature.

Applicants' claims have been amended to specify the injection of non-viral nucleic acids into the vasculature.

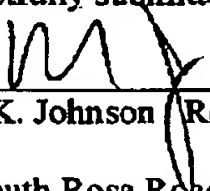
The Böhm *et al.* reference describes delivery of DNA where they obtain an immune response in 1 of 7 mice (Table 1 and in column 1 on page 953) and claim that i.v. injection is unreliable (page 950, column 2, Subcutaneous ...). Figures 2 and 3 on page 952 indicate no induction of immune response above control. On page 952 (column 1) Böhm *et al.* state "In contrast (to antigen protein), only the intramuscular or subcutaneous injection of HBsAg-encoding plasmid DNA reproducibly primed a MHC-1-restricted CTL (cytotoxic T lymphocyte) response." This reference is explicit in its statements that Applicants' method will not work or is unreliable because it only provided an immune response in 1 of 7 animals. In contrast, Applicants state on page 41, lines 24-25 that "the classic injection of plasmid DNA directly into skeletal muscle is not nearly as effective at generating an antibody response."

Applicants have amended their claims to obviate the reference by positively reciting: "generating the immune response in a majority of mammals injected for the purpose of utilizing the immune response."

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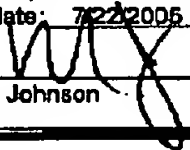
The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-7, 9-12 and 25-27 should be allowable. Applicants respectfully request a timely Notice of Allowance be issued in the case.

Respectfully submitted,



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Mark Johnson